

## **REMARKS**

### I. *Status of the claims*

Claims 1, 3, 5, 6, 9, 10, and 21-54 are pending. Claims 1, 6, 21, 29, and 49 have been amended. No new matter has been introduced by way of the amendments to the claims.

### II. *Telephonic interview*

The undersigned and the Applicant wish to thank Examiners Shibuya and DiRamio for the cordial and productive telephonic interview of February 25, 2010. The Examiners' helpful comments and suggestions were instrumental in preparing this Amendment. During the interview, Applicant's representative and the Examiners discussed the patentable differences between the claimed invention and the immunochromatographic devices disclosed in U.S. Patent No. 6,534,320 to Ching. In particular, Applicant's representative discussed the fact that Ching does not disclose or otherwise contemplate an affinity chromatography strip, as presently claimed, having a flowable component which, when entirely immersed in a buffer solution optionally comprising a fourth bio-reagent, forms a discrete volume at a first location that:

- (i) comprises said first bio-reagent;
- (ii) is denser than the buffer solution;
- (iii) does not diffuse rapidly into the buffer solution; and
- (iv) slowly rolls, under the influence of gravity, over said planar surface along said longitudinal axis in the direction of a second location.

Subsequent to the telephonic interview, Examiner DiRamio transmitted suggested claim amendments to the undersigned that could overcome the rejections of record. The suggested amendments have been incorporated into claim 1.

### III. *The rejection under 35 U.S.C. § 102(b) should be withdrawn*

Claims 1, 3, 5, 6, 9, 10, 21, 23-25, 36-45, and 54 stand rejected under 35 U.S.C. § 102(b) over Ching and U.S. Patent No. 5,602,040 to May *et al.* for the reasons set forth on pages 3-7 of the Office Action.

Applicant respectfully points out that Ching and/or May do not teach or otherwise suggest each and every feature recited in amended claim 1. In particular, neither reference discloses or otherwise contemplates a flowable component which, when entirely immersed in a buffer solution optionally comprising a fourth bio-reagent, forms a discrete volume at a first location that:

- (i) comprises said first bio-reagent;
- (ii) is denser than the buffer solution;
- (iii) does not diffuse rapidly into the buffer solution; and
- (iv) slowly rolls, under the influence of gravity, over said planar surface along said longitudinal axis in the direction of a second location.

The claimed affinity-chromatography strip has a structure and a function that are different than the structures and functions of Ching and May's devices. The structure of the claimed affinity-chromatography strip takes advantage of gravity to move the first bio reagent contained in the flowable component down from the first location to the second location having the second immobilized component.

Ching and May do not anticipate the claimed affinity-chromatography strip in the first place, because they lack a flowable component having the features recited in claim 1. Second, the devices described by Ching and May rely on a different phenomenon, namely, capillary action to move the sample and a solvent up along a solid phase material. *See*, Ching at 9:13-19 ("The method also employs a chromatographic medium having *capillarity* and the capacity for chromatographic solvent transport of non-immobilized reagents and reactive sample components by means of a selected chromatographic solvent including a reaction site including an immobilized reagent capable of binding a member selected from the group consisting of the substance to be analyzed and the colloidal particle labelled material.") (emphasis added); *see also* May at 2:36-45 ("The invention also provides an analytical method in which a device as set forth in the proceeding paragraph is contacted with an aqueous liquid sample suspected of containing the analyte, such that the sample permeates by *capillary action* through the porous solid phase material via the first zone into the second zone and the labelled reagent migrates therewith from the first zone to the second zone, the presence of analyte in the sample being determined by observing the extent (if any) to which the labelled reagent becomes bound in the second zone.") (emphasis added).

Since neither Ching nor May teach or otherwise suggest each and every feature recited in amended claim 1, neither reference anticipates claim 1 and the claims that depend therefrom. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejections under 35 U.S.C. § 102(b) over the Ching and May references.

IV. *The rejections under 35 U.S.C. § 103(a) should be withdrawn*

Claim 22 stands rejected under 35 U.S.C. § 103(a) over Ching and U.S. Patent No. 6,723,500 to Yu for the reasons set forth on pages 8 and 9 of the Office Action. Claims 26, 35, and 46 stand rejected under 35 U.S.C. § 103(a) over Ching in view of Publ. U.S. Appl. No. 2003/0207442 to Markovsky *et al.* for the reasons set forth on page 9 of the Office Action. Claims 27-31 and 47-51 stand rejected 35 U.S.C. § 103(a) over Ching in view of Markovsky and further in view of U.S. Patent No. 7,329,738 to Lee *et al.* for the reasons set forth on pages 10 and 11 of the Office Action. Claims 32 and 52 stand rejected under 35 U.S.C. § 103(a) over Ching in view of Markovsky and further in view of U.S. Patent No. 5,731,157 to Miller *et al.* for the reasons set forth on page 12 of the Office Action. Finally, claims 33 and 53 stand rejected under 35 U.S.C. § 103(a) over Ching in view of Markovsky and further in view of Publ. U.S. Appl. No. 2002/0024195 to Hubscher *et al.* for the reasons set forth on page 12 of the Office Action.

As an initial matter, Ching does not teach or otherwise contemplate immersing his device in buffer, such that the zone containing the sample to be analyzed is also immersed in the buffer. Further, as noted above, the devices described by Ching are fundamentally different than the claimed affinity-chromatography strip. First, the devices described by Ching do not have a flowable component, much less a flowable component comprising the features recited in claim 1 (e.g., denser than the buffer solution; does not diffuse rapidly into the buffer solution; and slowly rolls, under the influence of gravity). Accordingly, the devices described by Ching are structurally different than the claimed affinity-chromatography strip. Second, as noted above, the devices described in Ching work by capillary action, instead of by gravity, as presently claimed. Accordingly, Ching's devices are functionally different than the claimed affinity-chromatography strip.

None of the secondary references cited in the Office Action reconcile the fundamental deficiencies in Ching's teachings. For example, Hubscher describes "lateral flow" migration of the sample. *See, e.g.*, paragraph [0054]. The Yu reference discloses capillary action through a porous membrane. *See, e.g.*, column 7, lines 49 to column 8, line 27. Markovsky discloses a membrane which utilizes lateral capillary flow of a sample. *See, e.g.*, paragraphs [0006], [0008] and [0010]. Further, paragraph [0011] describes that the invention is for use in a generally horizontal position. Miller describes an ELISA technique in which a sample is added to an

immobilized substance (*e.g.*, antibody) prior to a labeled substance being added. *See, e.g.*, column 3, lines 57 to column 4, line 9. Finally, Lee discloses two detection methods – an ELISA based method and a membrane based method. *See, e.g.*, column 16, line 21 to column 18, line 51. The membrane based methods utilize a porous member through which capillary communication occurs. *See, e.g.*, column 17, lines 25 to 36.

Most of the references cited by the Patent Office, like Ching, work by capillary action. In addition, none of the references teach or otherwise contemplate immersing their devices in buffer, such that the zone containing the sample to be analyzed is also immersed in the buffer. Finally, none of those references teach or otherwise contemplate a flowable component having the features recited in claim 1. Accordingly, Ching alone, or in combination with Yu, Markovsky, Lee, Miller, and/or Hubscher, does not render the claimed invention obvious. Applicant therefore respectfully requests that the Examiner withdraw the rejections under 35 U.S.C. § 103(a) over the cited references.

In view of the foregoing, it is believed that this application is now in condition for allowance, and a Notice thereof is respectfully requested.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 955-1500. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

Hunton & Williams, L.L.P.

Dated: March 9, 2010

By:



Ricardo J. Moran, Ph.D.  
Registration No. 48,732

HUNTON & WILLIAMS LLP  
1900 K Street, N.W. Suite 1200  
Washington, D.C. 20006-1109  
(202) 955-1500 (telephone)  
(202) 778-2201 (facsimile)